OAH 65-0900-31227

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

In the Matter of Good Shepherd Lutheran Home (IIDR)

RECOMMENDED DECISION

This matter came before Administrative Law Judge Ann O'Reilly for an Independent Informal Dispute Resolution (IIDR) meeting on April 15, 2014. The parties submitted an additional exhibit on April 16, 2014. The record closed on April 16, 2014.

Christine R. Campbell, Registered Nurse and Nurse Evaluator II, appeared on behalf of the Minnesota Department of Health (Department). The following individuals also participated in the IIDR on behalf of the Department: Mary Cahill, Planner Principal with the Department's Division of Compliance Monitoring; and Lisa Ciesinski, RN, Special Investigator.

Susan Schaffer, Attorney at Law, appeared on behalf of Good Shepherd Lutheran Home (Good Shepherd or Facility). Bruce Glanzer, President, CEO and Administrator; Kathy Holtberg, RN, Director of Nursing; Kumaree Johnson, RN, Assistant Director of Nursing; and Jacqueline Barber, RN Case Manager, also appeared on behalf of the Facility.

Based on the arguments and submissions of the parties at the IIDR, and the contents of the record, the Administrative Law Judge makes the following:

RECOMMENDATION

It is respectfully recommended that:

1. The Commissioner delete Tag F-225 because the evidence does not establish a deficient practice by the Facility.

2. The Commissioner delete Tag F-226 because the evidence does not establish a deficient practice by the Facility.

3. The Commissioner affirm Tag F-323 and affirm the seriousness level assigned to the citation.

Dated: April 29, 2014

_s/Ann O'Reilly_____
ANN O'REILLY
Administrative Law Judge

Reported: Digitally Recorded
No transcript prepared

NOTICE

Under Minn. Stat. § 144A.10, subd. 16(d)(6), this Recommended Decision is not binding upon the Commissioner of Health. Pursuant to Department of Health Information Bulletin 04-07, the Commissioner must mail a final decision to the Facility, indicating whether or not the Commissioner accepts or rejects the Recommended Decision of the Administrative Law Judge within 10 calendar days of receipt of this Recommended Decision.

FINDINGS OF FACT

1. Good Shepherd is a skilled nursing facility located in Sauk Rapids, Minnesota.[1] The Facility has fewer than 62-beds and is organized into eight separate "households" or units.[2] The units are staffed by permanent employees who have regular shifts.[3] According to the Facility, the breakdown of permanent staff into smaller, assigned units promotes better oversight of nursing care.[4]

2. This matter arises out of an abbreviated state compliance survey completed on the Facility on September 18, 2013.[5] The survey was conducted as a result of a self-report by the Facility related to a fall suffered by one of its elderly residents on August 22, 2013.[6]

3. The compliance survey resulted in the issuance of a Statement of Deficiencies which cited four violations: Tag F-225 (related to the timely reporting of alleged neglect); Tag F-226 (related to the implementation of policies and procedures

[1] Testimony (Test.) of Bruce Glanzer.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] Exs. 1 and E.
[6] Test. of Lisa Ciesinski.

requiring the reporting of alleged neglect); Tag F-282 (related to compliance with resident care plans); and Tag F-323 (related to accident hazards and prevention).[7] The Facility does not challenge the issuance of Tag F-282.

Incident Resulting in Deficiency Tags

4. R1 is an 89-year-old woman who resides at the Facility.[8] R1 suffers from severe dementia.[9] Due to her age, and physical and mental condition, R1 is at risk of falls.[10] As a result, R1's care plan requires that all transfers be performed by at least two staff using an extra small, divided leg sling with a full mechanical lift.[11]

5. The mechanical lift used by the Facility for R1 is a 1998 PAL Professional Assistance Lift Pro-1 Model PC3504.[12] The lift device is comprised of a mechanical lift and sling.[13] The patient is seated in the sling, which is attached to the lift arm.[14] The lift arm moves the patient, who is seated in the sling, from one place to another, such as from the bed to a chair and vice versa.[15]

6. The sling has four loops or straps which attach it to the lift arm – two loops on the top located by the patient's shoulders and two loops on the bottom located by the patient's legs.[16] The loops fasten onto D-shape, carabiner-like[17] hooks on the lift arm.[18] The hooks secure the sling to the lift.[19] The hooks have a moveable hinged piece that opens and closes the hook.[20] The loop from the sling is slipped through the hinged piece on the hook to secure the sling to the lift arm.[21] The hinge is designed to allow the loop to be easily slipped into the D-shaped hook, and to close so as to prevent the loop from dislodging.[22]

7. On August 22, 2013, at approximately 4:00 p.m., two nursing assistants, NA-A and NA-B, were transferring R1 from her bed to her wheelchair using the mechanical lift, as directed by R1's care plan.[23] Once R1 was placed into the sling, NA-A secured the two loops closest to R1's legs onto the hooks of the lift arm.[24] NA-B

[7] Exs. 1 and E.
[8] *Id.*; Test. of L. Ciesinski.
[9] Id.
[10] Test. of L. Ciesinski.
[11] Exs. 1 and E.
[12] Test. of B. Glanzer.
[13] Test. of L. Ciesinski.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] Carabiner is generally defined as "a D-shaped ring with a spring catch on one side, used for fastening ropes in mountaineering." *See,* www.dictionary.com.
[18] Ex. 24.
[19] *Id.*
[20] *Id.*
[21] Test. of B. Glanzer.
[22] *Id.*
[23] Test. of J. Barber; Exs. 2 and 8.
[24] *Id.*

secured the hooks closest to R1's shoulders.[25] Both NA-A and NA-B believed the sling was secured into the hooks on the lift.[26] NA-A double-checked the two leg hooks but did not double-check the shoulder hooks.[27] NA-B believed the shoulder hooks were properly secured, but did not double-check the shoulder hooks before R1 was lifted.[28]

8. NA-A was operating the lift mechanism on the machine and NA-B was holding the wheelchair as R1 was raised from the bed.[29] As R1 was being lifted, the right shoulder strap dislodged from the lift hook and R1 slipped out of the sling, falling to the floor.[30] R1 hit her head on the lift and received a small, one centimeter laceration.[31] R1 complained of no other injuries.[32] R1's head cut was treated with an ice pack, and no bandage was necessary.[33]

9. NA-A and NA-B immediately notified the Registered Nurse (RN) Case Manager on duty for the unit, Jacqueline Barber.[34] Barber examined R1 to assess her for injuries.[35] R1 had a normal range of motion for both legs and arms, and did not complain of pain.[36]

10. After assessing and treating R1, Barber conducted an interview of NA-A and NA-B about the incident.[37] NA-A and NA-B assured Barber that they had attached the sling to the hooks correctly, and neither assistant could explain the cause of the hook's failure.[38]

11. Barber then verified that NA-A and NA-B had properly followed R1's care plan.[39] Barber confirmed that R1's care plan required the use of the lift and that the sling used was the correct size for R1.[40] Barber also inspected the sling and lift for defects.[41] Barber found that the sling, hooks, and lift were all in proper working condition and showed no deficiencies.[42] Maintenance records for the lift also indicated that the lift was properly serviced and maintained.[43] Accordingly, Barber could not concretely determine what caused one loop to discharge from the lift hook.[44]

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[25] *Id*.
[26] *Id.*
[27] Test. of C. Ciesinski.
[28] *Id.*
[29] Test. of J. Barber; Exs. 2 and 8.
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] Test. of J. Barber.
[35] *Id*.; Exs. 2 and 8.
[36] *Id.*
[37] Test. of J. Barber.
[38] *Id.*
[39] *Id*.; Exs. 2 and 8.
[40] *Id.*
[41] *Id.*
[42] *Id*.
[43] Ex. 21.
[44] Test. of J. Barber.

12. Based upon her assessment, Barber determined that there was no evidence to suggest neglect or a failure to follow the patient's care plan.[45]

13. Barber immediately met with Kathy Holtberg, the Facility's Director of Nursing, to advise her of the incident and to discuss the Facility's reporting requirements.[46] Barber and Holtberg agreed that the incident was the result of an accident, and did not indicate any suspected neglect, abuse, or mistreatment.[47] In addition, because R1's injury appeared quite minor, the nurses decided that the incident did not require a report to the Facility Administrator or the Department.[48]

14. As required by the Facility's Abuse Prevention Plan, Barber completed the Facility's Vulnerable Adult Investigative Form.[49] The form asks, "Is this an allegation of mistreatment of a resident?" to which Barber answered, "no."[50] Accordingly, no report was made to the Facility Administrator or the Department.[51]

Discovery of Additional Injury

15. At approximately 3:10 a.m. on August 23, 2013, nearly 12 hours after the fall, R1 awoke.[52] R1 was "crying, screaming, and shaking with cares."[53] A licensed practical nurse (LPN) administered pain medication but R1 continued to have pain throughout the night.[54]

16. When Barber arrived for her shift the next morning (August 23, 2013), she was advised of R1's condition.[55] Barber contacted a nurse practitioner and requested that R1 be seen.[56] The nurse practitioner examined R1 that afternoon ordered an X-ray.[57] The X-ray showed that R1 had fractured her right hip.[58]

Report to Facility Administrator and Department

17. Upon learning the extent of R1's injuries, Barber and Holtberg notified Bruce Glanzer, the Facility's Administrator, of R1's fall and injuries.[59] While Glanzer and Holtberg did not consider the accident to be a reportable incident of suspected

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[45] *Id.*
[46] Test. of J. Barber; Test. of Kathy Holtberg.
[47] *Id*.
[48] *Id*.
[49] Ex. 3.
[50] *Id.*
[51] Test. of J. Barber; Test. of K. Holtberg.
[52] Ex. I at 1-2.
[53] *Id.* at 1.
[54] *Id.* at 1-3.
[55] Test. of J. Barber.
[56] *Id*.; Ex. 5.
[57] Test. of J. Barber; Exs. I-17 and 5.
[58] Exs. I-17 and 5.
[59] Test. of J. Barber; Test. of K. Holtberg; Ex. 3.

neglect, abuse, mistreatment, or misappropriation of resident property, they decided to report the matter to the Department because of the seriousness of R1's injuries.[60]

18. At 2:31 p.m. on August 23, 2013, within 24 hours of the fall, Assistant Director of Nursing, Kumaree Johnson, reported the incident to the Department.[61] The Facility then completed a full investigation into the incident.[62]

19. After completing its investigation, the Facility reported the results of its investigation to the Department on August 28, 2013, within five working days of the incident.[63]

Abbreviated Standard Survey

20. As a result of the Facility's self-report, the Department conducted an abbreviated standard survey on September 18, 2013.[64]

21. Lisa Ciesinski, an RN and Special Investigator with the Department's Office of Health Facility Complaints, conducted the survey.[65] Ciesinski inspected the subject mechanical lift and found no defects.[66] She also observed the use of mechanical lifts for six residents at the Facility, including R1.[67] Of the six residents observed, three of the residents (R1, R2, and R3) were in R1's unit (Memory Lane) and three (R4, R5, and R6) were residents of another unit in the Facility.[68]

22. Ciesinski found that the Facility was correctly utilizing the lift for R1, R3, R5 and R6.[69] However, Ciesinski observed that staff was using the incorrect size sling for two of the residents, R2 and R4.[70] R2's care plan required the use of a medium size sling and staff was using an extra-large size sling.[71] R4's care plan required a small

[60] Test. of B. Glanzer; Test. of K. Holtberg.
[61] Test. of K. Holtberg; Exs. E-3 and 7. There is some discrepancy in the record as to when the Administrator was notified of the incident and when the report was made to the Department. In its Statement of Deficiencies, the Department asserts that the Facility reported the incident to the Department at 2:31 p.m. on August 23, 2013. *See* Ex. E-3. Whereas, the Facility's records indicate that the Administrator was notified of the incident at 2:45 p.m. on August 23, 2013. Testimony at the IIDR indicated that the report to the Administrator and the report to the Department occurred in short order, with the report to the Administrator occurring first. In any event, both the report to the Administrator and the report to the Department occurred sometime between 2:30 and 2:45 p.m. on August 23, 2013, within 24 hours of the fall.
[62] Ex. 2.
[63] Exs. 2 and 7.
[64] Ex. E.
[65] Test. of L. Ciesinski.
[66] *Id.*
[67] *Id*.; Exs. 1 and E.
[68] *Id*.
[69] *Id*.
[70] *Id*.
[71] *Id*.

sling and staff was utilizing a medium size sling.[72] Using too large of a sling places a patient at risk of slipping out of the sling and being injured.[73]

23. As a result of these deficiencies, Ciesinski issued Tag F-282, which charges a failure to provide services in accordance with a resident's written plan of care.[74] The Facility does not dispute the issuance of Tag F-282 and that tag is outside the scope of this IIDR.[75]

24. Ciesinski also interviewed NA-A and NA-B about the incident occurring on August 22, 2013.[76] NA-A was working at the Facility on the day of the survey, but NA-B was not.[77] NA-A stated that he fastened the legs straps of the sling onto the lift and that NA-B fastened the shoulder straps.[78] NA-A confirmed that he double-checked the leg hooks, and he acknowledged that it was Facility policy to check that the loops are secure before lifting a patient.[79] NA-A believed the shoulder straps were securely fastened onto the lift hooks, but he did not double-check the shoulder straps because NA-B had fastened those straps to the lift hooks.[80]

25. Ciesinski interviewed NA-B on October 4, 2013.[81] NA-B stated that she fastened R1's shoulder straps to the mechanical lift on August 22, 2013, and that she believed they were secure before they lifted R1 from the bed.[82] However, NA-B denied that she double-checked the hooks after fastening them, as was required by Facility policy.[83]

26. Ciesinski also interviewed Jacqueline Barber, the RN Case Manager in R1's unit at the time of the fall. Barber stated that NA-A and NA-B immediately notified her of the incident on August 22, 2013, and she assessed R1 for injuries immediately after the fall.[84] Barber explained that she then conducted an immediate investigation into the incident.[85] While Barber was unable to determine the exact cause of the lift strap's failure, she did confirm that NA-A and NA-B followed R1's care plan.[86] Barber explained that, based upon her investigation, and because R1's injuries appeared minimal, it was her determination that a report to the Facility's Administrator was not required.[87]

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[72] *Id.*
[73] Test. of L. Ciesinski.
[74] *Id.*; Exs. 1 and E.
[75] Test. of B. Glanzer.
[76] Test. of L. Ciesinski; Exs. 1 and E.
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*

27. Finally, as part of the survey, Ciesinski reviewed the Facility's policies and procedures regarding the use of mechanical lifts, as well as the reporting of suspected abuse, neglect, mistreatment, and misappropriation.[88]

Facility's Mechanical Lift Policies and Procedures

28. The Facility maintains a Mechanical Lift Transfer Policy.[89] The Policy requires that staff "[f]ollow manufacturer's instructions for the specific lift."[90] It also refers staff to "Skill: 38 from the Nursing Assistant Curriculum."[91]

29. The Skill: 38 from the nursing assistant training curriculum sets forth nine "pre-steps" for operating a mechanical lift.[92] The steps include "[c]heck all safety features such as location of hooks and fasteners" and "[a]ttach sling to lift according to manufacturer's instructions."[93]

30. The lift at issue in this case was purchased by the Facility in 1998.[94] The Facility denies that it maintains a copy of the manufacturer's instructions for that lift model, due to its age.[95] However, a manual was obtained by the Department for a PAL Professional Assistance Lift Pro-1 PC350 – a newer model of the subject lift.[96] The manual cautions: "**IMPORTANT**MAKE SURE ALL FOUR LOOPS FROM THE SLING ARE ON THE HOOKS OF THE HANGER BEFORE LIFTING A PATIENT OR RESIDENT."[97]

31. An updated version of the same manual (obtained by the Department from the manufacturer), adds the additional instruction: "Once there is slight tension on the straps[,] check to make sure all four loops are still on the hooks before lifting."[98] The Facility denies maintaining a copy of this manual, as it is not for the particular lift used on R1.[99]

32. The Department also obtained a publication from the federal Food and Drug Administration (FDA) entitled, "Patient Lifts Safety Guide."[100] The Guide states:

> Ensure all clips or loops are secure and will stay attached as patient is lifted

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[88] *Id*.
[89] Ex. 19.
[90] *Id*.
[91] *Id.*
[92] Ex. 13.
[93] *Id*.
[94] Test. of B. Glanzer.
[95] Argument of Susan Schaffer; Test. of K. Holtberg.
[96] Ex. I-18-30. It is unclear how this manual came into the Department's possession.
[97] Ex. I-20.
[98] Ex. I-46.
[99] Argument of S. Schaffer.
[100] Exs. I-48-65 and 15.

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Examine all hooks and fasteners to ensure they will not unhook during use

Double-check position and stability of straps and other equipment before lifting patient

Ensure clips, latches and bars are securely fastened and structurally sound

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Lift patient two inches off the surface to make sure patient is secure. Check the following:

> Sling straps are confined by guard on sling bar and will not disengage….[101]

Lift Training for NA-A and NA-B

33. NA-B began working at the Facility on June 14, 2013, and completed mechanical lift orientation training on June 17, 2013.[102] The Facility's "Lift Orientation on Hire" training materials provide direction for staff on how to use a mechanical lift.[103] The document instructs: "Attach all 4 hooks to the harness....Recheck all 4 hoops a second time before lifting a resident."[104]

34. As part of the new employee lift training, the Facility administers a post-training quiz to ensure the employee understood the training materials.[105] NA-B's post-test included the following question:

> Staff must recheck all 4 hooks a second time before moving the resident in the sling to assure the resident is safe.
>
> True
> False[106]

35. NA-B correctly answered "true" to the question.[107]

36. The quiz also asked:

> To whom do you report a lift concern?
>
> a. Case Manager/Supervisor
> b. Team Leader if Case Manager/Supervisor is not in facility

[101] *Id.*
[102] Exs. 10 and 11.
[103] Ex. 11.
[104] *Id.*
[105] *Id*.
[106] *Id*.
[107] *Id*.

c. The other NARS you are working with that day
d. Both a. and b.[108]

37. NA-B correctly answered "d" to the question, indicating that she understood her reporting requirements.[109]

38. NA-A was hired in May 2013, and completed new employee lift training on May 21, 2013.[110] Like NA-B, NA-A correctly answered the above-quoted questions on his post-training test.[111]

Manufacturer Training Sessions in June 2013

39. As the Director of Nursing for the Facility, Holtberg keeps current on Centers for Medicare and Medicaid Services (CMS) decisions and guidance materials to ensure that the Facility is compliant with all federal and state regulations.[112]

40. In the summer of 2013, prior to the incident at issue in this action, Holtberg noticed that lift accidents were the subject of some recent CMS cases.[113] To ensure that her staff was properly trained and compliant with lift procedures, Holtberg contacted SMT Health Systems (SMT), the manufacturer of the Pro Lifts used by the Facility.[114] Holtberg arranged for the manufacturer to conduct training sessions for staff at the Facility.[115]

41. On June 20, 2013, a SMT representative conducted a training session for all Facility staff.[116] The training session included a "Lift Program Skills Check[-]Off" document.[117] The instructions provided by the company did not specifically require "double checking" the lift hooks to ensure that the sling is securely fastened.[118] Instead, the check-off list states:

> Fasten the loops of the sling to the Y-Beam hangers, make sure you use the same color loop on each 'J' hook and carefully listening [sic] for the safety clip to engage.[119]

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[108] *Id.*
[109] *Id.*
[110] Exs. 18 and 20.
[111] Ex. 20.
[112] Test. of K. Holtberg.
[113] *Id.*
[114] *Id.*
[115] *Id.*
[116] Test. of K. Holtberg; Ex. 16.
[117] Ex. 16.
[118] *Id.*
[119] *Id.*

42. The manufacturer's training session occurred approximately one month before the incident at issue in this case.[120] NA-B attended the manufacturer's training.[121]

Post-Incident Lift Training for NA-B and Remedial Measures

43. Immediately after R1's fall on August 22, 2013, Barber reviewed the Facility's lift procedure with NA-A and NA-B to ensure that they fully understood the requirements for using a mechanical lift.[122] Both nursing assistants confirmed their knowledge of the policies and procedures related to the use of mechanical lifts.[123] Nonetheless, because NA-B was quite shaken by the incident, Barber required NA-B to attend a "refresher" training session on nursing assistant "Skill: 38" related to mechanical lifts.[124]

44. To prevent a similar incident from occurring, the Facility initiated a new policy for the use of lifts which required that both staff members operating a lift double-check all four hooks to ensure that the sling is firmly fastened to the lift arm before elevating a patient.[125] Barber spoke with all staff members present in her unit and advised them of the new policy.[126] She directed them to relay the information to nurses working the subsequent shifts.[127]

45. In addition, to ensure all employees were advised of the new policy, the Facility employed its "Teachable Moment" practice.[128] The procedure involves posting "Teachable Moment" memoranda at the nursing stations in each of the Facility's units.[129] "Teachable Moment" memoranda use recent, real-life examples of incidents to educate staff regarding specific safety or training issues.[130]

46. On August 26, 2013, the Facility posted a "Teachable Moment" memorandum in each of the Facility's units.[131] The "Teachable Moment" memorandum stated:

> Please implement double checks for all mechanical lift transfers. After you and the other person have hooked up the lift slings you must double check each other's straps to make sure they are secured to prevent one coming loose during the transfer.[132]

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[120] *Id*.
[121] Ex. 12.
[122] Test. of J. Barber.
[123] *Id*.
[124] Ex. 13.
[125] Test. of K. Holtberg; Test. of J. Barber.
[126] Test. of J. Barber.
[127] *Id.*
[128] *Id*.
[129] *Id.*
[130] *Id*.
[131] Test. of J. Barber; Ex. 22.
[132] Ex. 22.

47. The "Teachable Moment" memorandum required all staff to sign and acknowledge the directive to ensure all staff members were advised of the policy change.[133]

Reporting Policies and Procedures

48. In addition to policies and procedures regarding the use of mechanical lifts, the Facility developed and maintains abuse prevention and reporting policies and procedures. The Facility's Abuse Prevention Plan (Plan) includes training guidelines, as well as procedures for reporting suspected incidents of abuse, mistreatment, maltreatment, neglect, and misappropriation of resident property.[134]

49. The Plan includes a Decision Making Guide for Incident Reporting (Decision Guide); an Incident Reporting Form and Investigative Guide; and an Accident/Injury Reporting Policy.[135]

50. The Plan instructs that:

1. Incidents are reported, documented, and investigated internally using the Good Shepherd Lutheran Home Incident Reporting policy and procedure – see Appendix E.

2. Not all incidents need to be reported to an outside agency. Appendix F provides a Decision Making Guide to help determine what types of incidents to report. Incidents where it is determined that maltreatment may have occurred **must** be reported to the county Common Entry Point (CEP). See 'External Reporting' below.

3. All allegations of mistreatment, abuse, neglect, or misappropriation of resident property must immediately be reported by phone to the administrator or designee as appointed by the administrator in his/her absence….[136]

51. The External Reporting Policy of the Plan requires that:

All <u>alleged incidents</u> of maltreatment are reported to the appropriate agency immediately[,] as required[,] and all necessary corrective actions, depending on the results of the investigation, are taken. 'Immediately' means as soon as possible.[137]

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[133] *Id.*
[134] Ex. 9.
[135] *Id.*
[136] *Id*. at 18 (emphasis supplied in original).
[137] *Id.* at 19 (emphasis supplied in original).

52. The Accident/Injury Reporting Policy states that:

> All accidents/injuries involving Good Shepherd Lutheran Home residents are reported as soon as possible to the team leader/RN Case Manager/Nursing Supervisor. The RN supervisory/RN Case Manager should be notified immediately to start investigating and interviewing staff and the resident.[138]

53. The purpose of the Decision Guide is to assist staff in determining which types of incidents must be reported to supervisors, the Facility Administrator, and the Department.[139] The Decision Guide specifically states that falls require an employee to follow the "Incident Reporting" policy and procedure, as well as "immediately" conduct a thorough investigation and document the findings on an incident form and the resident's medical records.[140] "Immediately" is defined in the Decision Guide to mean "as soon as possible, but no longer than 24 hours from the time initial knowledge that the incident occurred has been received."[141]

54. The Plan defines "neglect" to include both the federal definition found in 42 C.F.R. § 488.301, and the state definition, found in Minn. Stat. § 626.5572, subd. 17.[142] "Neglect" is defined in 42 C.F.R. § 488.301 as:

> [F]ailure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

55. Under the Minnesota Vulnerable Adults Act, "neglect" is defined as:

> (a) The failure or omission by a caregiver to supply a vulnerable adult with care or services, including but not limited to, food, clothing, shelter, health care, or supervision which is:
>
> > (1) reasonable and necessary to obtain or maintain the vulnerable adult's physical or mental health or safety, considering the physical and mental capacity or dysfunction of the vulnerable adult; and
> >
> > (2) which is not the result of an accident or therapeutic conduct[; or]
>
> (b) The absence or likelihood of absence of care or services, including but not limited to, food, clothing, shelter, health care, or supervision necessary to maintain the physical and mental health of the vulnerable adult which a reasonable person would deem essential to obtain or maintain the

[138] *Id.* at 42.
[139] *Id.* at 33.
[140] *Id.*
[141] *Id.*
[142] *Id.* at 14.

vulnerable adult's health, safety, or comfort considering the physical or mental capacity or dysfunction of the vulnerable adult.[143]

56. The Plan delineates certain "exceptions/exemptions" to the abuse and neglect reporting requirements.[144] The Plan states:

> The following items would be considered exceptions or exemptions and would not be considered *abuse, neglect or financial exploitation*:
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> ***
>
> (2) When the action that has occurred is considered an accident. An accident is defined as a sudden, unforeseen, and unexpected event which is not likely to occur and which could not have been prevented by exercise [of] due care and that the facility and employee is in compliance with laws and rules relevant to the occurrence or event.
>
> ***
>
> (7) An individual makes an error in the provision of therapeutic conduct that results in injury or harm, which required the care of a physician, and:
>
> > (a) The necessary care is provided in a timely fashion as dictated by the condition of the resident;
> >
> > (b) If after receiving care, the resident can be reasonably expected, as determined by the attending physician, to return to his or her preexisting condition;
> >
> > (c) The error is not part of a pattern of errors by the individual;
> >
> > (d) The error is immediately reported and recorded following the facility's procedures;
> >
> > (e) The facility identifies and takes corrective action and implements corrective action and measures designed to reduce the risk of further occurrence of the error or similar errors; and
> >
> > (f) The actions taken are sufficiently documented for review and evaluation by facility staff and outside agencies having legal authority to review such documentation.[145]

57. The Plan's "accident" exception appears to come from the Minnesota Vulnerable Adult Act, which defines "accident" as:

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[143] Minn. Stat. § 626.5572, subd. 17.
[144] Ex. 9 at 15.
[145] *Id.* (emphasis supplied in original).

> [A] sudden, unforeseen, and unexpected occurrence or event which:
>
> (1) is not likely to occur and which could not have been prevented by exercise of due care; and
>
> (2) if occurring while a vulnerable adult is receiving services from a facility, happens when the facility and the employee or person providing services in the facility are in compliance with the laws and rules relevant to the occurrence or event.[146]

58. Under Minnesota law, an "accident" is not required to be reported to the county's common entry point as "maltreatment."[147]

59. The Plan's "therapeutic" exception also appears to come from Minnesota law which exempts errors in the provision of therapeutic conduct from the definition of "neglect" for purposes of maltreatment reporting.[148]

60. The Department acknowledges that the Facility properly developed policies and procedures for: (1) screening and training employees; (2) protection of residents; and (3) the prevention, identification, investigation, and reporting of abuse, neglect, mistreatment, and misappropriation of resident property.[149] However, the Department asserts that the policies and procedures were not effectively implemented on August 22, 2013, to ensure a timely report to the Facility Administrator and Department.[150]

Federal Regulatory Background

61. The Social Security Act mandates the establishment of minimum health and safety standards that must be met by providers and suppliers participating in the Medicare and Medicaid Programs.[151] Participation requirements for skilled nursing and long-term care facilities are set forth in 42 C.F.R. § 483, subp. B.

62. The Centers for Medicare and Medicaid Services (CMS) is a federal agency within the U.S. Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid.

63. CMS assures compliance with the participation requirements through "surveys" conducted by state agencies, which have been delegated the responsibility for such action.[152] In Minnesota, the state survey agency is the Minnesota Department of

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[146] Minn. Stat. § 626.5572, subd. 3.
[147] Minn. Stat. § 626.557, subd. 3a(3).
[148] *See* Minn. Stat. § 626.5572, subd. 17(c)(4) and (5).
[149] Argument of Christine Campbell; Test. of L. Ciesinski.
[150] Argument of C. Campbell.
[151] 42 U.S.C. §§ 1302 and 1395hh. *See also*, 42 C.F.R. § 483.
[152] *See e.g.,* 42 U.S.C. § 1864(a); 42 C.F.R. § 488.11.

Health (Department). The state survey agency reports any "deficiencies" to the CMS on a standard form called a "Statement of Deficiencies."[153]

64. A "deficiency" is a failure to meet a participation requirement set forth in the Social Security Act or 42 C.F.R. § 483, subp. B.[154] Deficiencies are cited as alpha-numeric "tags," which correspond to a regulatory requirement in 42 C.F.R. § 483. The citations are commonly referred to as "F-Tags" because they relate to the survey enforcement provisions set forth in 42 C.F.R. § 488, subp. F.

65. To assist state agencies in conducting surveys, CMS publishes a State Operations Manual (SOM).[155] The SOM, including its Appendix P, provides guidance to state survey agencies, as well as regulated facilities, as to how the CMS interprets the various rules and regulations.[156]

66. When a violation of rule or "deficiency" is identified, the state survey agency must then make a determination as to the seriousness of that deficiency.[157] The seriousness of the deficiency determines the remedy or sanction imposed.[158] The seriousness of the deficiency depends both on its "scope" and its "severity."[159]

67. Guidance on scope and severity is set forth in the SOM at Appendix P, Deficiency Categorization.[160] Pursuant to 42 U.S.C. § 488.404, and the SOM, there are four levels of severity: Level 1, Level 2, Level 3, and Level 4. Level 1 is the lowest level of severity; and Level 4 is the highest level of severity.[161]

68. A Level 1 deficiency results in no actual harm but has potential for minimal harm.[162] A Level 2 deficiency results in no actual harm but has potential for more than minimal harm, but harm that does not cause immediate jeopardy.[163] A Level 3 deficiency results in actual harm, but harm that does not cause immediate jeopardy.[164] A Level 4 deficiency results in immediate jeopardy to the resident's health or safety.[165]

69. Scope has three levels: Isolated, pattern, and widespread.[166]

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[153] *See e.g.,* Ex. 5.
[154] 42 C.F.R. § 488.301.
[155] *See* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf
[156] *Id.*
[157] 42 C.F.R. § 488.404.
[158] *Id.*
[159] *Id. See also,* Ex. C (SOM at Appendix P).
[160] *Id.*
[161] 42 U.S.C. § 488.404; SOM at Appendix P (Ex. C).
[162] SOM at Appendix P (Ex. C).
[163] *Id.*
[164] *Id.*
[165] *Id.*
[166] *Id.*

70. Scope and severity are then arranged into a Scope and Severity Grid in the SOM (Grid).[167] The Grid is a three-column, four-row grid with the scope listed in columns along the bottom (isolated, pattern, and widespread); and the severity levels listed in ascending order along the side (Level 1 at the bottom, proceeding up to Level 4 at the top).[168] Each cell on the Grid is then given a letter designation, signifying the seriousness level.[169] "A" is the least serious level of deficiency and "L" is the most serious level of deficiency.[170] The fourth level of the Grid (designations J, K, and L) is reserved for those deficiencies which place residents in immediate jeopardy.[171] Levels F through L are considered substandard quality of care.[172] The Grid appears as follows:[173]

	Isolated	Pattern	Widespread
Immediate jeopardy to resident health or safety	J PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	K PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	L PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2
Actual harm that is not immediate jeopardy	G PoC Required* Cat. 2 Optional: Cat. 1	H PoC Required* Cat. 2 Optional: Cat. 1	I PoC Required* Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt.
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D PoC Required* Cat. 1 Optional: Cat. 2	E PoC Required* Cat. 1 Optional: Cat. 2	F PoC Required* Cat. 2 Optional: Cat. 1
No actual harm with potential for minimal harm	A No PoC No Remedies Commitment to Correct Not on HCFA-2567	B PoC	C PoC

Substandard quality of care in any deficiency in 42 CFR 483.13 Resident Behavior and Facility Practices, 42 CFR 483.15 Quality of Life, or 42 CFR 483.25, Quality of Care that constitutes immediate jeopardy to resident health or safety; or, a pattern of or widespread actual harm that is not immediate jeopardy; or, a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

Substantial compliance

[167] Ex. O.
[168] *Id.*
[169] *Id.*
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.*

71. As set forth above, the seriousness level translates into a "required" or "optional" remedy category.[174] Under the SOM, Remedy Category 1 includes directed plans of correction, monitoring, and/or in-service training. Remedy Category 2 includes denial of payments and/or monetary penalties.[175] Remedy Category 3 includes temporary management, termination, and/or monetary penalties.[176]

Issuance of Statement of Deficiencies and Facility Appeal

72. Based upon its investigation and review of the Facility's policies and procedures, the Department concluded that the Facility violated 42 C.F.R. § 483.13(c)(2) (Tag F-225); 42 C.F.R. 483.13(c) (Tag F-226); 42 C.F.R. § 483.20(k)(3)(ii) (Tag F-282); and 42 C.F.R. § 483.25(h) (Tag F-323).[177] The Department determined that:

- the Facility staff failed to timely report suspected neglect to the Facility Administrator and the Department (Tag F-225);
- the Facility failed to implement written policies and procedures requiring the reporting of mistreatment, abuse, neglect, and misappropriation (Tag F-226);
- the Facility staff failed to provide services in accordance with a resident's care plan (Tag F-282); and
- the Facility failed to ensure that the resident environment remains as free of accident hazards as possible, and that each resident receives adequate supervision and assistance devices to prevent accidents (Tag F-323).[178]

73. As a result, the Department issued a Statement of Deficiencies citing four F-Tags: Tag F-225, Tag F-226, Tag F-282, and Tag F-323.[179]

74. The Department determined that the severity of the deficiencies cited in Tags F-225, F-226, and F-282 was a Level 2.[180] According to the SOM's Appendix P, severity Level 2 is:

> [N]oncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or

[174] *Id.*
[175] *Id.*
[176] *Id.*
[177] Exs. 1 and E.
[178] *Id.*
[179] *Id.*
[180] *Id*.

> reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.[181]

75. The Department further determined that the scope of the deficiencies cited in Tags F-225, F-226, and F-282 was "isolated."[182] According to the SOM's Appendix P:

> Scope is isolated when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations.[183]

76. Relying upon the CMS Scope and Severity Grid, the Department assigned Tags F-225, F-226, and F-282 to a seriousness level "D."[184]

77. With respect to Tag F-323, the Department determined that the severity of the deficiency cited was a Level 3.[185] According to the SOM's Appendix P, severity Level 3 is:

> [N]oncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequences to the resident.[186]

78. The Department further determined that the scope of the deficiency cited in Tag F-323 was "isolated."[187]

79. Relying upon the CMS Scope and Severity Grid, the Department assigned Tag F-323 to a seriousness Level "G."

80. The Facility timely filed a request for an Independent Informal Dispute Resolution proceeding pursuant to Minn. Stat. § 144A.10, subd. 16. In its appeal, the Facility does not dispute or challenge Tag F-282.

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[181] Ex. C.
[182] Exs. 1 and E.
[183] Ex. C.
[184] Exs. 1 and E.
[185] *Id.*
[186] Ex. C.
[187] Exs. 1 and E.

Postscript

81. The incident involving R1 was the Facility's first accident occurring as a result of the use of a mechanical lift.[188]

82. R1 has since recovered from the fall.[189] She continues to reside at the Facility.[190] NA-A continues to work at the Facility.[191] NA-B resigned from her employment effective December 14, 2013.[192]

Based on the submissions of the parties at the IIDR, the contents of the record, and the Findings of Fact noted above, the Administrative Law Judge makes the following:

CONCLUSIONS OF LAW

1. Good Shepherd Lutheran Home is a skilled nursing facility subject to the federal Social Security Act and 42 C.F.R. Parts 483 and 488.

2. All skilled nursing home facilities regulated under the Social Security Act must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and the misappropriation of resident property.[193]

3. "Neglect" is defined by federal rule as the "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness."[194]

Tag F-225: Reporting of Alleged Mistreatment, Neglect, Abuse, or Misappropriation

4. Pursuant to 42 C.F.R. § 483.13(c)(2), a regulated facility "must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to the other officials in accordance with State law through established procedures (including to the state survey and certification agency)."

5. "Immediately" is defined in the SOM as "as soon as possible, but ought not exceed 24 hours after discovery of the incident, in the absence of a shorter State time frame requirement."[195]

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[188] Test. of J. Barber.
[189] Test. of J. Barber.
[190] *Id*.
[191] *Id.*
[192] Ex. 14.
[193] 42 C.F.R. § 483.13(c).
[194] 42 C.F.R. § 488.301.
[195] Ex. F-3.

6. The facility must also thoroughly investigate all alleged instances of mistreatment, neglect, abuse, or misappropriation, and must prevent further potential abuse while the investigation is in progress.[196] The results of the investigation must be reported to the facility administrator or his/her designated representative and to the Minnesota Department of Health within five working days of the incident.[197]

7. R1's fall from the mechanical lift on August 22, 2013, was not the result of the Facility's failure to provide goods and services to R1 which were necessary to avoid physical harm, mental anguish, or mental illness. The facts and circumstances surrounding the fall did not indicate any alleged or suspected neglect, abuse, mistreatment, or misappropriation of resident property. As a result, the Facility was not subject to the reporting requirements set forth in 42 C.F.R. § 483.13(c)(2) – (4). It is, therefore, recommended that Tag F-225 be **DELETED**.

Tag F-226: Implementation of Abuse Prevention and Reporting Procedures

8. Regulated facilities must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.[198]

9. Regulated facilities must develop and operationalize policies and procedures for screening and training employees; for the protection of residents; and for the prevention, identification, investigation, and reporting of abuse, neglect, mistreatment, and misappropriation of property.[199] The purpose is to assure that the facility is doing all that is within its control to prevent occurrences.[200]

10. The facility's policies and procedures must include seven components: "screening, training, prevention, identification, investigation, protection, and reporting/response."[201] In addition to the development of policies and procedures addressing each of the seven components, the facility must effectively implement those policies.[202]

11. Good Shepherd developed written policies and procedures that prohibit mistreatment, neglect, abuse, and misappropriation of resident property. Said policies contained all seven components required by 42 C.F.R. § 483.13(c) and the SOM, including screening, training, prevention, identification, investigation, protection, and reporting/response.

12. Good Shepherd implemented its policies and procedures on August 22 and 23, 2013, despite the fact that the incident at issue did not involve alleged neglect,

[196] 42 C.F.R. § 483.13(c)(3).
[197] 42 C.F.R. § 483.13(c)(4).
[198] 42 C.F.R. § 483.13(c).
[199] Ex. G (SOM).
[200] *Id.*
[201] *Id.*
[202] *Id*.

abuse, mistreatment, or misappropriation. The Facility's staff reported the incident to the Administrator and to the Department within 24 hours of the fall. The Facility immediately investigated the incident; followed the Facility's documentation and investigative procedures; and prevented further harm while the investigation was in process by instituting an additional mechanical lift policy. In addition, the Facility timely reported the results of the investigation to the Department within five working days of the incident. As a result, the Facility was not in violation of 42 C.F.R. § 483.13(c), and it is respectfully recommended that Tag F-226 be **DELETED**.

Tag F-323: Accident Hazards, Supervision, and Assistive Devices

13. All residents in regulated facilities must receive, and the regulated facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and care plan.[203]

14. A regulated facility must ensure that the resident environment remains as free of accident hazards as is possible, and that each resident receives adequate supervision and assistance devices to prevent accidents.[204] The intent of 42 C.F.R. § 483.25(h), is "to ensure the facility provides an environment that is free from accident hazards over which the facility has control[,] and provides supervision and assistive devices to each resident to prevent *avoidable* accidents."[205]

15. An "accident" is defined in the SOM as "any unexpected or unintentional incident, which may result in injury or illness to a resident."[206] An "avoidable accident" occurs when a facility fails to:

- Identify environmental hazards and individual resident risk of an accident;
- Evaluate and analyze the hazards and risks;
- Implement interventions consistent with a resident's needs, goals, plan of care, and current standards of practice to reduce the risk of an accident; and/or
- Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.

16. If an accident is avoidable, a Facility is in violation of 42 C.F.R. § 483.25(h).

[203] 42 C.F.R. § 483.25.
[204] 42 C.F.R. § 483.25(h)(1)-(2).
[205] Ex. H (emphasis added).
[206] Ex. H.

17. The fall that occurred in this case was the result of an avoidable accident. While the Facility: (1) properly identified the hazards and risks associated with mechanical lifts; (2) evaluated and analyzed the hazards and risks; and (3) initiated interventions which included training, policies, and procedures, the Facility failed to monitor the effectiveness or implementation of the interventions to ensure that its staff was complying with all safety requirements. As a result, the incident that occurred on August 22, 2013, was an avoidable accident, resulting in a violation of 42 C.F.R. § 483.25(h).

Remedy

18. A regulated facility is subject to remedial action if it is not in "substantial compliance" with one or more regulatory standards.[207] A facility is not in substantial compliance if there is a deficiency that creates at least the "potential for more than minimal harm" to one or more residents.[208]

19. The evidence establishes that Good Shepherd was not in substantial compliance with 42 C.F.R. § 483.25(h). As a result, R1 suffered actual harm which did not arise to immediate jeopardy. Said harm is consistent with Level 3 severity.

20. The evidence further establishes that the scope of the incident was isolated and not systematic, as it was the first time that a fall occurred at the Facility related to the use of a mechanical lift. Therefore, based upon the Scope and Severity Grid set forth in the SOM, it is respectfully recommended that Tag F-323 be affirmed at a seriousness Level "G."

MEMORANDUM

Tag F225: Failure to Report Alleged Neglect [42 C.F.R. § 483.13(c)(2)]

Federal regulations require that a Facility ensure that all alleged incidents of mistreatment, neglect, abuse, and misappropriation of resident property be reported "immediately" to the facility administrator and to other officials, including the state survey agency.[209] CMS interprets "immediately" to be "as soon as possible" but not to exceed 24 hours after discovery of the incident.[210]

The Department asserts that the incident at issue in this case involved suspected or alleged "neglect," not abuse, mistreatment, or misappropriation. Therefore, the definitions of abuse, mistreatment, and misappropriation are not addressed herein.

[207] 42 C.F.R. § 488.400.
[208] 42 C.F.R. § 488.301.
[209] 42 C.F.R. § 483.13(c)(2).
[210] Ex. F-3.

"Neglect" is defined by federal rule as the "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness."[211] The Facility, however, urges the Department to adopt the definition is set forth in Minnesota law. The Minnesota Vulnerable Adults Act defines "neglect" as:

> (a) The failure or omission by a caregiver to supply a vulnerable adult with care or services, including but not limited to, food, clothing, shelter, health care, or supervision which is:
>
> > (1) reasonable and necessary to obtain or maintain the vulnerable adult's physical or mental health or safety, considering the physical and mental capacity or dysfunction of the vulnerable adult; and
> >
> > (2) *which is not the result of an accident or therapeutic conduct*.
>
> (b) The absence or likelihood of absence of care or services, including but not limited to, food, clothing, shelter, health care, or supervision necessary to maintain the physical and mental health of the vulnerable adult which a reasonable person would deem essential to obtain or maintain the vulnerable adult's health, safety, or comfort considering the physical or mental capacity or dysfunction of the vulnerable adult.[212]

Unlike the federal definition, Minnesota law expressly excepts accidents and therapeutic conduct from the definition of neglect.[213] The State definition would be exceedingly helpful in the determination of this case. However, because this action involves the application of federal Medicare/Medicaid standards, not the State's maltreatment laws, the more restrictive, federal definition of neglect prevails.

Under the federal definition, "neglect" includes a failure to provide goods and services that are necessary for a resident's care, health, and safety. The definition of neglect does not, however, equate negligence to neglect. Negligence and neglect are two different concepts in law.

In its common use, neglect is a failure to provide assistance where assistance is required, such as a failure to supply food, care, or supervision; whereas, negligence is the failure to exercise reasonable care in the provision of such assistance.[214] While neglect of a duty of care may arise to negligence, not all negligence (i.e., failure to exercise reasonable care) amounts to neglect.

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[211] 42 C.F.R. § 488.301.
[212] Minn. Stat. § 626.5572, subd. 17.
[213] *Id.*
[214] According to *Black's Law Dictionary*, "neglect" is defined as "[a]n omission to do or perform some work, duty, or act." abridged 6th ed. (West 1991). "Negligence" is defined as "the failure to use such care as a reasonably prudent and careful person would use under similar circumstances." *Id. See also*, CIVJIG 25.10 ("Negligence is the failure to use reasonable care."); *Seim v. Garavalia,* 306 N.W.2d 806, 810 (Minn. 1981).

The fall that occurred in this case was caused by either a defect in the lift hook or human error. The Facility immediately inspected the lift and determined that there was no defect in any of its components. Therefore, a preponderance of the evidence suggests that human error was to blame.

But even assuming that NA-B was negligent by failing to double-check to ensure that the sling was connected securely to the lift hook, none of the evidence of the incident suggested a failure to provide goods or services to R1. In fact, NA-A and NA-B were providing assistance services to R1 when the fall occurred. The staff was not neglecting R1. While an error in the provision of those services resulted in a serious injury to R1, the circumstances of the fall did not, at any point, indicate neglect.

The Department contends that even though the Facility ultimately determined that no neglect occurred, the Facility was obligated to report the incident to the Department immediately after it occurred because the fall may have been the result of neglect. Such contention ignores the reality of the events. Here, NA-A and NA-B immediately reported the incident to their nursing supervisor (Barber) as required by the Facility's Accident/Injury Reporting Policy. Barber examined and treated R1 for injuries; inspected the mechanical lift for defects; and interviewed the nursing assistants to determine the cause of the fall. Barber confirmed that: (1) two nursing assistants were operating the lift, as required by the Facility's mechanical lift policy; (2) both nursing assistants checked and believed the sling was securely fastened on the hooks before they lifted the resident; (3) the lift, sling, and hooks displayed no visible defects; and (3) R1's care plan was being correctly implemented by the use of the lift and the correct sling size. Thus, all of the evidence available to Barber suggested that the fall was the result of an accident, not neglect, abuse, or mistreatment.

Barber then conferred with her supervisor, the Director of Nursing, and both employees agreed that the facts were consistent with an accident, and did not present any suspicion of neglect. Thus, the supervising nurses made the informed decision that the incident did not require a report of abuse, neglect, mistreatment, or maltreatment, under state or federal law.

The federal reporting requirement set forth in 42 C.F.R. § 483.13(c)(2), applies to "*alleged* violations involving mistreatment, neglect, or abuse, including injuries of unknown source."[215] The regulation does not apply to *all* accidents and *all* injuries that occur in a facility. R1's injury was not an injury of unknown source,[216] and there was no indication that the injury was the result of neglect, abuse, or mistreatment. If 42 C.F.R.

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[215] 42 C.F.R. § 483.13(c)(2) (emphasis added).

[216] According to the SOM, an injury should be classified as an "injury of unknown source" when both of the following conditions are met:

(1) The source of the injury was not observed by any person **or** the source of the injury could not be explained by the resident; **and**

(2) The injury is suspicious because of the extent of the injury **or** the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) **or** the number of injuries observed at one particular point in time **or** the incidence of injuries over time.

See Ex. F-3 (emphasis supplied in original).

§ 483.13(c)(2) required the reporting of all accidents and injuries, the regulation would provide for the same. The fact that the regulation is limited to alleged mistreatment, neglect, abuse, and injuries of unknown origin, establishes that the regulation was not intended to apply to all accidents and injuries.

The Department's interpretation of 42 C.F.R. § 483.13(c)(2), would require all regulated facilities to instantaneously report all accidents and injuries without any time for contemplation or initial investigation. Such interpretation not only expands the express language of the regulation beyond its stated scope and intent, it imposes an unrealistic duty upon facilities. Accordingly, it is respectfully recommended that Tag F-225 be **DELETED**.

Tag F-226: Failure to Implement Reporting Policies and Procedures [Violation of 42 C.F.R. § 483.13(c)]

The Department contends that the Facility failed to properly implement its abuse prevention and reporting policies and procedures. While the Department concedes that the Facility developed policies and procedures compliant with the requirements of 42 C.F.R. § 483.13, the Department asserts that the Facility failed to ensure that its policies were followed and operationalized at the time of the subject incident.[217]

Federal regulations require that regulated facilities "develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property."[218] The policies and procedures must include seven major components: "screening, training, prevention, identification, investigation, protection, and reporting/response."[219]

In addition to the development of the policies and procedures, the facility must ensure that the policies and procedures are effectively implemented and operationalized.[220] According to the SOM, the purpose of the rule "is to assure that the facility is doing all that is within its control to prevent occurrences."[221]

In this case, the Department does not dispute that the Facility developed policies and procedures compliant with 42 C.F.R. § 483.13(c). Indeed, the Facility developed and had in place policies and procedures for screening and training staff, as well as policies and procedures for preventing, identifying, investigating, reporting, and protecting residents from incidents of abuse, neglect, mistreatment, and misappropriation of property. The Department, however, argues that the Facility failed to implement its policies and procedures when its staff failed to report the incident "immediately" to the Facility Administrator and the Department.

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[217] Because the Department conceded that the Facility's policies and procedures were compliant with 42 C.F.R. § 483.13, there is no need to address the development or adequacy of the Facility's policies and procedures.
[218] 42 C.F.R. § 483.13(c).
[219] *Id. See also*, Ex. G (SOM).
[220] *Id.*
[221] Ex. G.

Despite the fact that the subject incident did not indicate any alleged abuse, neglect, mistreatment, or misappropriation, the Facility did, indeed, implement and follow its policies and procedures in ultimately reporting the incident to the Department. In accordance with the Facility's Abuse Prevention Plan and Accident/Injury Reporting Policy, NA-A and NA-B immediately reported the incident to their nursing supervisor, RN Case Manager Barber. Barber, in turn, followed the Facility's protocol by immediately investigating the incident and interviewing staff to determine whether the incident could possibly be the result of abuse, neglect, or mistreatment. Based upon all the evidence available at that time, Barber concluded that the fall was the result of an accident, and that there was no evidence of suspected neglect, abuse, or mistreatment.

In compliance with the Facility's internal investigation and reporting procedures, Barber completed a Vulnerable Adult Investigation Form in which Barber acknowledged that the incident did not involve an allegation of mistreatment or an injury of an unidentified source. Barber then conferred with Holtberg, the Director of Nursing, and together the nursing supervisors concluded that the incident was an accident and did not involve any allegations of neglect, abuse, or mistreatment.

Nonetheless, as soon as Barber and Holtberg learned that R1's injuries involved more than just a minor cut, they immediately reported the incident to the Facility Administrator, who, in turn, reported the matter to the Department. The incident occurred at approximately 4:00 p.m. on August 22, 2013, and the report was made to the Department at 2:31 p.m. on August 23, 2013, within 24 hours of the fall.

In addition, immediately after the fall, the Facility conducted a thorough investigation, documented its findings, initiated a new policy to prevent similar incidents, and reported the results of its investigation to the Department within the required five days. All of these actions were in compliance with the Facility's own policies and procedures, as well as 42 C.F.R. § 483.13(c). Indeed, the Facility proceeded with all of its reporting policies and procedures, including making a report to the Department within 24 hours, even though a report was not required by federal law because the incident did not involve alleged abuse, neglect, or mistreatment.

There is simply no evidence of a defect in the implementation of the Facility's reporting policies and procedures. Facility staff followed the Facility's policies and procedures, and complied with 42 C.F.R. § 483.13(c). Accordingly, the Department has failed to show that the Facility was not in substantial compliance with the standard, and it is respectfully recommended that Tag F226 tag be **DELETED**.

Tag F-323: Failure to Mitigate Accident Hazard [Violation of 42 C.F.R. § 483.25(h)]

Federal regulations provide that a regulated facility must ensure that the resident environment remains as free of accident hazards as is possible, and that each resident receives adequate supervision and assistance devices to prevent accidents.[222]

[222] 42 C.F.R. § 483.25(h)(1)-(2).

According to the SOM, the intent of 42 C.F.R. § 483.25(h), is "to ensure the facility provides an environment that is free from accident hazards *over which the facility has control*[,] and provides supervision and assistive devices to each resident to prevent *avoidable* accidents."[223]

An "accident" is defined in the SOM as "any unexpected or unintentional incident, which may result in injury or illness to a resident."[224] The SOM differentiates between "avoidable accidents" and "unavoidable accidents."[225] An "avoidable accident" occurs when a facility fails to:

- Identify environmental hazards and individual resident risk of an accident…;
- Evaluate or analyze the hazards and risks;
- Implement interventions…consistent with a resident's needs, goals, plan of care, and current standards of practice to reduce the risk of an accident; and/or
- Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.[226]

"Unavoidable accidents" are defined in the SOM as accidents that occur despite the facility's efforts to identify the hazards and risks; evaluate or analyze the hazards and risks; implement interventions; and monitor and modify the interventions as necessary.[227] Under the direction of the SOM, if the accident in this case was "avoidable," then the Facility is subject to the deficiency tag. If, however, the accident was "unavoidable" and the Facility did everything it could to avoid the accident, then the deficiency should be deleted.

The evidence presented establishes that the Facility identified and evaluated the hazards associated with mechanical lifts, and initiated interventions, including training and policies and procedures, to address those hazards. First, the Facility conducted lift orientation for all new employees, which instructed staff on the proper use of mechanical lifts.[228] Such training expressly instructed staff to "recheck all 4 hoops a second time before lifting a resident."[229]

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[223] Ex. H at 1 (emphasis added).
[224] *Id.*
[225] *Id.* at 1-2.
[226] *Id.*
[227] *Id.* at 2.
[228] Exs. 11 and 17.
[229] *Id.*

Second, the Facility maintained a Mechanical Lift Transfer Policy, which is taught as part of "Skill: 38" of the nursing assistant training curriculum.[230] The training curriculum includes a post-test designed to ensure staff fully understand the training provided.[231] The post-test specifically addresses the requirement to "recheck all 4 hooks a second time before moving the resident."[232]

Third, in June 2013, two months prior to the incident in this case, the Facility specifically arranged for the lift manufacturer to conduct a special training session for all staff.[233] The purpose of the training was to reinforce the manufacturer's most updated directions for proper use of mechanical lifts. NA-B attended that training.

In addition, after the incident in this case, the Facility immediately modified the interventions and training to advise its staff of the risk and prevent similar incidents from occurring. The Facility immediately: (1) retrained NA-B on the use of mechanical lifts; (2) revised the Facility's lift policy to require that both nurses operating a lift re-check all four lift hooks before lifting a patient; and (3) utilized the "Teachable Moments" procedure to advise all nursing staff of change in policy.[234]

What the Facility failed to do, however, was monitor the effectiveness of its interventions to ensure that the lift procedures and policies were being fully implemented by staff. While NA-B believed that the sling was securely attached to the lift hook, NA-B acknowledged that she did not double-check the hooks, as required by the Facility's training materials. Accordingly, the Facility's training and policies were not being fully implemented by NA-B at the time of the fall.

Moreover, at the time of the abbreviated survey, which occurred several weeks after the incident in this case, the Department discovered that two of six lifts observed at the Facility were being used incorrectly by staff. Specifically, the wrong sling size was being used for two residents, placing those residents at risk for a fall from the sling. The survey occurred at a time when the Facility should have been most vigilant in supervising and monitoring its staff to ensure that all lifts were being operated correctly and in compliance with Facility policies and procedures.

The evidence thus establishes that employees were not fully implementing the lift training and policies established by the Facility, and better monitoring of those interventions could have prevented the accident in this case. Policies and training are only effective if they are consistently implemented and regularly monitored by the Facility. This requires oversight and supervision of staff.

Section 483.25(h) does not render a facility strictly liable for all accidents that occur in the facility, but it does require that a facility take all reasonable steps to ensure

[230] Exs. 13 and 19.
[231] Exs. 11 and 20.
[232] *Id.*
[233] Ex. 16.
[234] Exs. 13 and 22.

that a resident receives supervision and assistance devices designed to meet her needs, and to mitigate foreseeable risks of harm from accidents related to those devices.[235] Here, the Facility failed to take reasonable steps to mitigate foreseeable risks of harm by failing to monitor the effectiveness and implementation of its training, policies, and procedures. Evidence that the staff was incorrectly using lifts several weeks after the fall is evidence of a lack of effective monitoring and implementation of life policies and procedures. Consequently, the fall that occurred in this case was the result of an "avoidable accident," as defined in the SOM. The accident was, indeed, one that could have been avoided by the exercise of reasonable care and the full implementation of interventions. Accordingly, it is respectfully recommended that Tag F-323 be **AFFIRMED**.

Scope and Severity

It is undisputed that actual harm resulted from the accident, but that such harm did not arise to immediate jeopardy. R1 suffered a head laceration and a broken hip, and has since recovered. The evidence also establishes that the accident in this case was an isolated occurrence. This was the Facility's first and only fall resulting from a mechanical lift. Accordingly, the scope and severity of the deficiency is consistent with a seriousness Level G.

A. C. O.

[235] *See e.g., Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003).